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TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

2520-109P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

NEW 08/952475

INTERNATIONAL APPLICATION NO.  
PCT/JP96/01346INTERNATIONAL FILING DATE  
21 May 1996PRIORITY DATE CLAIMED  
21 May 1995TITLE OF INVENTION  
MEAT PRODUCTS WITH PLASMA-CHOLESTEROL-LEVEL SUPPRESSING PROPERTYAPPLICANT(S) FOR DO/EO/US  
MORIMATSU, Fumiki; KATSUDA, Shinichiro; SATO, Mikako; NAKAGAMI, Tatsuyoshi

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ has been transmitted by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

## Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A **FIRST** preliminary amendment.  
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:

☒ International Search Report (PCT/ISA/210)  
☒ Request (PCT/RO/101)  
☒ Two (2) sheets of formal drawings

NEW

PCT/JP96/01346

2520-109P

17. ☒ The following fees are submitted:

## BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):

Search Report has been prepared by the EPO or JPO ..... \$930.00

International preliminary examination fee paid to USPTO (37 CFR 1.482)  
..... \$720.00No international preliminary examination fee paid to USPTO (37 CFR 1.482)  
but international search fee paid to USPTO (37 CFR 1.445(a)(2)) ..... \$790.00Neither international preliminary examination fee (37 CFR 1.482) nor  
international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$1,070.00International preliminary examination fee paid to USPTO (37 CFR 1.482)  
and all claims satisfied provisions of PCT Article 33(2)-(4) ..... \$ 98.00

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## CALCULATIONS PTO USE ONLY

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\$ 130.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	16 - 20 =	0	X \$22.00
Independent claims	1 - 3 =	0	X \$82.00
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overpayment to Deposit Account No. 02-2448. A duplicate copy of this sheet is enclosed.NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR  
1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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## 特許協力条約に基づいて公開された国際出願

<b>(51) 国際特許分類6</b> <b>A23L 1/31, 1/29</b>	<b>A1</b>	<b>(11) 国際公開番号</b> <b>WO96/37119</b>  <b>(43) 国際公開日</b> <b>1996年11月28日(28.11.96)</b>
<b>(21) 国際出願番号</b> PCT/JP96/01346 <b>(22) 国際出願日</b> 1996年5月21日(21.05.96)  <b>(30) 優先権データ</b> 特願平7/146814 1995年5月21日(21.05.95) JP  <b>(71) 出願人 (米国を除くすべての指定国について)</b> 日本ハム株式会社(NIPPON MEAT PACKERS, INC.)(JP/JP) 〒541 大阪府大阪市中央区南本町3丁目6番14号 Osaka, (JP) <b>(71) 出願人 (米国についてのみ)</b> 中上昌代(NAKAGAMI, Masayo)(JP/JP) (中上辰芳(死亡)の相続人) 〒662 兵庫県西宮市仁川町6丁目2-3 Hyogo, (JP) <b>(72) 発明者; および</b> <b>(75) 発明者/出願人 (米国についてのみ)</b> 森松文毅(MORIMATSU, Fumiki)(JP/JP) 勝田新一郎(KATSUDA, Shinichiro)(JP/JP) 佐藤三佳子(SATO, Mikako)(JP/JP) 〒300-26 茨城県つくば市緑ヶ原3丁目3番 日本ハム株式会社 中央研究所内 Ibaraki, (JP)		<b>(72) 発明者</b> 中上辰芳(NAKAGAMI, Tatsuyoshi) (死亡、相続人は中上昌代) <b>(74) 代理人</b> 弁理士 廣瀬孝美(HIROSE, Takayoshi) 〒530 大阪府大阪市北区西天満5丁目13番3号 高橋ビル3号館6階 Osaka, (JP)  <b>(81) 指定国</b> CA, US, 欧州特許(AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE),  添付公開書類 国際調査報告書 請求の範囲の補正の期限前であり、補正書受領の際には再公開される。
<b>(54) Title : MEAT PRODUCT HAVING EFFECT OF INHIBITING INCREASE IN BLOOD CHOLESTEROL</b>  <b>(54) 発明の名称</b> 血中コレステロール上昇抑制作用を有する食肉製品  <b>(57) Abstract</b> <p>A meat product having an effect of inhibiting an increase in blood cholesterol which has a fat content reduced by 1/2 or less compared with the conventional products and contains soybean protein. Because of having a reduced fat content and containing soybean protein capable of lowering blood cholesterol therein, the meat product can exert the effect of improving blood lipids without detriment to the texture or preference.</p>		

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## SPECIFICATIONS

MEAT PRODUCTS WITH PLASMA-CHOLESTEROL-LEVEL  
SUPPRESSING PROPERTY

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## TECHNICAL FIELD

This invention provides meat products. More particularly, the invention provides the meat products possessing plasma-cholesterol-level suppressing property and favorable texture and taste.

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## BACKGROUNDS OF THE INVENTION

Malignant neoplasm, heart and cerebrovascular diseases have been recognized as three major causes of adults' death of late. Particularly, number of patients and death due to ischemic heart diseases including cardiac infarction tend to increase. Basal diseases of the ischemic heart diseases are arterial sclerosis and hyperlipidemia (particularly, hypercholesterolemia). Increases in amount of animal-fat consumption have been regarded as one of causes of these diseases. According to Japanese nutrition census carried out in 1992, increment of animal-protein consumption was praised, but problems to be caused by increment of animal-fat consumption as well as that of energy-intake ratio due to it was pointed out.

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To suppress plasma-cholesterol level by diet, it is important to limit intake of cholesterol and animal fat themselves. It has been well known that plasma-cholesterol levels depend upon not only intake of dietary fat but also that of protein. It has been reported that intake of vegetable protein, particularly soy protein, suppresses plasma-cholesterol level.

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As described above, excessive intake of meat products may cause the ischemic heart diseases. However, the meat products are protein-rich, easy-to-eat, delicious and durable foods. The meat products, particularly sausage,

contain 10-30% fat, which contributes to supply energy and express such sensory properties as texture and taste characteristic to the sausage.

From these viewpoints, it has been desired to develop meat products, of which fat content is reduced without decrement of favorable characteristics of the meat products. For such purposes, the meat products with less fat content have been developed. However, no meat product with favorable texture and taste has ever been developed.

Reduction of fat contents in the meat products may be one of means to prevent the ischemic heart diseases. However, more positive measures to suppress the plasma-cholesterol level have been desired.

The present invention was accomplished on the basis of such background. The purposes of the invention were to develop the meat products with reduced fat contents, plasma-cholesterol-level suppressing property and conventionally accepted favorable texture and taste.

## DISCLOSURE OF THE INVENTION

The present invention provides meat products, of which fat contents are less than halves of those of conventional meat products. Addition of soy protein with plasma-cholesterol-suppressing property is characteristic of the meat products of the invention.

Another invention is a use method comprising administration of the above-described meat products to man.

By reducing fat content and fortifying soy protein with plasma-cholesterol-level suppressing property, the meat products of the invention can improve plasma lipid levels of man. Moreover, the meat products of the invention possess characteristically favorable texture and taste.

## BRIEF DESCRIPTION OF FIGURES

Figure 1 shows periodical changes in total plasma-cholesterol levels of man administered the meat product of the invention.

Figure 2 shows periodical changes in plasma-HDL-cholesterol levels of man administered the meat product of the invention.

5 Figure 3 shows periodical changes in plasma-triglyceride levels of man administered the meat product of the invention.

#### THE BEST MODE FOR APPLYING THE INVENTION

10 The present invention is made up as described above. Fat contents of the meat products of the present invention are reduced to halves of those of conventional meat products on weight basis. For example, in case of Wiener sausage, fat content of conventional one is 24.8 g against a 100-g product (see Japanese food nutrient analysis tabel, the fourth edition). On the contrary,  
15 that of the invention is adjusted to less than 12.4 g.

Fat content can properly be adjusted in course of sausage manufacturing. Generally, sausage emulsions are prepared by adding salt, nitrite and the like to raw meat, curing the meat in a chilled room for one day, grinding the cured meat and fat individually, chopping the cured meat with seasonings and other  
20 additives in a bowl cutter, and then adding the fat. Consequently, fat content can be adjusted, when fat is added to mixture comprising the chopped meat, the seasonings and other additives. Likewise, fat contents of other meat products can properly be adjusted in course of manufacturing.

It is desirable for the meat products of the invention to contain vegetable  
25 oil. A ratio of vegetable-oil and animal-fat contents is desirably adjusted to approximately 1:1 on weight basis. Soy-bean oil, rape-seed oil, safflower oil, sesame oil, rice-bran oil, olive oil, corn oil, sunflower oil, cotton-seed oil, peanut oil, salad oil and the like, and/or mixed and prepared one of these oil are examples of the vegetable oil. By using the vegetable oil, the meat  
30 products of the invention can be fortified with essential fatty acids including

linoleic and linolenic acids and various unsaturated fatty acids possessing physiological functions. As shown by fatty-acid compositions in Table 2 and by adjusting a ratio of vegetable-oil and animal-fat contents to approximately 1:1 on weight basis, the meat products of the invention contain reduced amounts of saturated fatty acids possessing total plasma-cholesterol-level increasing property. Moreover, the meat products of the invention contain more mono- (e.g., oleic acid) and poly-unsaturated fatty acids, which have been reported to reduce the total plasma-cholesterol level, than conventional products. Such characteristics are considered to exhibit the plasma-cholesterol-suppressing properties of the meat products of the invention. Furthermore, a ratio of saturated : mono-unsaturated : poly-unsaturated fatty-acid contents is improved from 3 : 3.5 : 1 of the conventional products to 1.3 : 3 : 1 of the products of the invention. The latter value satisfies a ratio of 1 : 1.5 : 1 of a well-balanced fatty-acid ratio, suggesting that the meat products of the invention can be sources of mono-unsaturated fatty acids, which has been difficult to be taken through diet.

Examples of favorable fatty-acid composition (%) are as the following: myristic acid, 0.5 - 1.5; myristoleic acid, 0 - 0.2; pentadecanoic acid, 0; palmitic acid, 13.0 - 22.0; palmitoleic acid, 1.5 - 2.5; heptadecanoic acid, 0 - 0.3; heptadecenoic acid, 0 - 0.3; stearic acid, 5.0 - 9.0; oleic acid, 24.0 - 60.0; linoleic acid, 9.0 - 45.0; linolenic acid, 0.2 - 6.0, arachidic acid, 0.1 - 1.0; icosenoic acid, 0.2 - 1.0; and arachidonic acid, 0 - 0.2.

The meat products of the invention contain soy protein. Examples of soy protein are soy-protein isolate, textured soy-protein, soy-protein concentrate, defatted soy flour and the like. Of them, the soy-protein isolate is favorably used because of its high protein content and excellent binding property. Although amounts of soy protein to be added may vary, those sufficient enough to suppress plasma-cholesterol levels are used. To 100-g final products, usually 1- to 20-g, preferably 5- to 15-g, and more preferably 8- to 10-g soy protein is added depending on protein contents of soy-protein

preparations and kinds of meat products. Addition of less than 1-g soy protein may not always exhibit a cholesterol-suppressing effect. Although soy-protein addition of more than 20 g causes no problem, the cholesterol-suppressing effects are attained by addition of the soy protein less than 20 g.

- 5        Examples of the meat products of the invention are sausages including pork sausage, Wiener sausage, Frankfurt sausage, Bologna sausage, loaves, hams, bacons, corned beef, hamburger steak, meat balls, such delicatessen as Gyoza and Shumai, fresh sausage, bratwurst, ground meat, seasoned meat and the like. Cooked, semi-cooked and/or raw meat products are included.
- 10      These meat products are conventionally prepared except for both reduction of fat contents and addition of soy protein.

#### INDUSTRIAL APPLICABILITY

- 15        The present invention effectively provides the meat products with favorable texture and taste and plasma-cholesterol-level suppressing property.

- Particularly, if both vegetable oil and animal fat are simultaneously added to the meat products as lipids, the products are favorable sources of
- 20      unsaturated fatty acids which have been reported to exhibit physiological functions including total plasma-cholesterol-suppressing property and the like, since the products contain huge amounts of unsaturated and poly-unsaturated fatty acids. Consequently, the meat products of the invention are useful as functional food, health food and the like.

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#### EXAMPLES

- The present invention will be specifically explained in detail with actual experiments and examples, but the scope of the invention is not restricted to
- 30      them.



### Example 1

Lymph nodes and cartilages were carefully removed from porcine thigh meat. A 3.5-kg portion of the thigh meat was ground and blended with 50-g salt, 0.4-g sodium nitrite, 10-g sodium polyphosphate and 800-g ice/water with constant agitation for 5 min at 20 rpm. After that, mixture was transferred into a clean container and allowed to stand for 24 h at 5°C.

Similarly, lymph nodes and cartilages were carefully removed from porcine shoulder meat. A 1.5-kg portion of the shoulder meat was chopped with 1.0-kg ice/water, 70-g salt, and 300-g soy-bean oil for 40 sec in a bowl cutter, and then mixture were chopped with 750-g soy-protein isolate (New Fujipro HN, Fuji-Seiyu, Inc., Japan) and 1.0-kg ice/water for 60 sec. Thus, paste-like preparation was prepared.

The paste-like preparation and the ground porcine thigh meat allowed to stand for 24 h were transferred into a blender and then blended for 3 min at 20 rpm. Thus, sausage emulsion was prepared. The sausage emulsion was stuffed into sheep casing, smoked, cooked to an internal temperature of 70°C, cooled and chilled. Thus, a meat product (sausage) of the invention was prepared.

Nutrient analysis data and fatty-acid components of the prepared sausage are shown in Tables 1 and 2, respectively. As a comparison, those of conventional sausage are also listed (cited from Japanese food nutrient analysis tabel, the fourth edition).

Fatty-acid components of sausages prepared with other vegetable oil in place of the soy-bean oil are listed in Table 3.

Table 1

	Sausage of the invention	Conventional sausage
Moisture	62.6	55.5
Protein	17.4	13.1
5 Fat	12.1	24.8
Carbohydrate	4.7	3.8
Fiber	0.3	0
Ash	2.9	2.8
Energy (Kcal)	206	304

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Table 2

	Fatty acid	Fatty-acid composition (%)	
		Sausage of the invention	Conventional sausage
15	Myristic acid C14:0	0.8	1.4
	Myristoleic acid C14:1	0.1	0.1
	Pentadecanoic acid C15:0	0.0	0.1
	Palmitic acid C16:0	16.5	23.5
	Palitoleic acid C16:1	1.6	2.8
20	Heptadecanoic acid C17:0	0.2	0.4
	Heptadecenoic acid C17:1	0.2	0.3
	Stearic acid C18:0	7.1	12.7
	Oleic acid C18:1	30.6	43.8
	Linoleic acid C18:2 (n-6)	32.1	12.0
25	Linolenic acid C18:3 (n-3)	4.5	0.7
	Arachidic acid C20:0	0.2	0.2
	Icosenoic acid C20:1	0.3	0.9
	Arachidonic acid C20:4 (n-6)	0.1	0.3
	Others	5.5	0.8
30	P/S ratio	1.48	0.34
	Saturated fatty acid	25	38
	Mono-unsaturated fatty acid	33	48
	Poly-unsaturated fatty acid	37	13

P/S ratio: Poly-unsaturated fatty acids (C18:1,C18:3,C20:4) / Saturated

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fatty acids (C14:0, C15:0, C16:0, C17:0, C18:0, C20:0)

Table 3

Fatty acid	Fatty-acid composition (%)										
	Rape- seed oil	Saff- lower oil	Sesame oil	Rice- bran oil	Olive oil	Corn oil	Sun- flower oil	Cotton seed oil	Peanut oil	Salad oil	
Myristic acid	0.8	0.8	0.8	0.9	0.8	0.8	0.8	1.2	0.8	0.8	
Myristoleic acid	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
Pentadecanoic acid	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Palmitic acid	13.2	14.9	15.8	19.4	16.3	16.9	14.6	21.6	17.3	14.2	
Palitoleic acid	1.6	1.5	1.6	1.6	1.9	1.5	1.5	1.9	1.6	1.6	
Heptadecanoic acid	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	
Heptadecenoic acid	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	
Stearic acid	5.9	6.4	7.8	5.9	6.7	6.1	7.0	6.3	7.2	6.3	
Oleic acid	48.8	24.8	38.3	39.2	57.4	36.0	27.8	27.4	40.5	43.5	
Linoleic acid	15.6	44.8	27.7	22.8	9.6	30.7	41.1	34.2	23.2	20.7	
Linolenic acid	6.0	0.4	0.6	1.0	0.7	1.1	0.7	0.6	0.4	5.6	
Arachidic acid	0.3	0.1	0.5	0.4	0.1	0.1	0.1	0.2	1.0	0.3	
Icosenoic acid	1.0	0.2	0.4	0.5	0.2	0.2	0.2	0.3	0.9	0.8	
Arachidonic acid	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
Others	6.0	5.3	5.8	7.5	5.4	5.6	5.4	5.5	6.4	3.4	
P/S ratio	1.06	2.01	1.13	0.89	0.43	1.32	1.85	1.18	0.89	1.21	
Saturated fatty acid	20	22	25	27	24	24	23	30	27	22	
Mono-unsaturated fatty acid	52	27	41	42	60	38	30	30	43	46	
Poly-unsaturated fatty acid	22	45	28	24	10	32	42	35	24	26	

P/S ratio: Poly-unsaturated fatty acids (C18:1, C18:3, C20:4)/Saturated fatty acids (C14:0, C15:0, C16:0, C17:0, C18:0, C20:0)

## Example 2

As for the sausage prepared in Example 1 (Test variable # 1), its sensory properties were evaluated. Cholesterol-suppressing property was also examined by feeding it to laboratory animals.

5 To examine effects of not only soy protein but also lipids, sausage containing pork protein/soy-bean oil without soy protein (Test variable # 2) and sausage containing pork protein/lard (Test variable # 3, conventional sausage) were also prepared as controls. Crude-protein and crud-fat contents of these sausage were adjusted to those of Test variable # 1.

10 Nutrient analysis data (g/100 g) of these sausage are shown in Table 4.

Table 4

	Test variable # 1	Test variable # 2	Test variable # 3
15 Moisture	62.6	62.6	62.6
Protein	17.4	17.4	17.4
Fat	12.1	12.1	12.1
Carbohydrate	4.7	5.1	5.1
Fiber	0.3	0	0
Ash	2.9	2.8	2.8
20 (Soy protein)	(7.9)	0	0

### ① Sensory evaluation

Sensory characteristics of the sausages of Test variables # 1, # 2 and # 3 were examined by well-trained panel (five men and five women ranging 24 to 40 yr old). Test samples were served as usual, namely immediately after simmering the sausages for 5 min. Overall acceptance was scored by a preference scale (Fact scale). Appearance, color, flavor and texture were scored by 5-point scales according to Japanese Agricultural Standard. The results are shown in Table 5.

30 As shown in Table 5, the sausage of the invention was judged favorable in respects of appearance, color, flavor and texture. Its binding property was also excellent.

Table 5

	Appearance	Color	Flavor	Texture	Overall acceptance
#1	4.8	4.7	4.8	4.8	Most favorable
#2	4.6	4.1	4.0	4.1	Poor color and flavor
5 #3	4.8	4.7	4.4	4.1	Good color and flavor, but poor texture (tough) and binding property

## ② Evaluation of cholesterol-suppressing effect

Crude-fat and crude-protein contents of the sausages were determined by Soxhlet and Kjeldahl methods, respectively. Using lyophilized and ground sausages, experimental diets were prepared by adjusting their protein and fat contents to 20% and 12%, respectively. Ingredients of three diets are listed in Table 6.

The feeding experiments were carried out on male SD rats, of which body weight ranged from 120 to 160 g. After preliminary rearing for one week, the diets and water were fed ad libitum (ten rats each). Twenty-eight days later, blood was collected and major organs were eviscerated for macroscopic examination.

The collected blood was conventionally examined for total cholesterol (T-chol.), HDL cholesterol (HDL-chol.), free cholesterol (F-chol.), triglyceride (TG), and phospholipid (PL) with an automatic serum analyzer (AU-510, Olympus, Inc., Japan).

No abnormality was macroscopically observed in such major organs as liver, kidney, spleen, stomach, intestine, heart and lung.

Plasma-lipid levels were analyzed and their data are shown in Table 7 (mean  $\pm$  standard deviation, unit: mg/dl). Statistical analysis among the test variables were carried out by a method of Scheffe et al.

As shown in Table 7, levels of T-chol., HDL-chol., F-chol., TG and PL of the rats fed the sausage of the invention (Test variable #1) were lower than those of the control rats (Test variables #2 and #3). Suppression of plasma-cholesterol levels by administrating the sausage of the invention was proved.

Table 6

	Test variable #1	Test variable #2	Test variable #3
Animal protein	10.0	20.0	20.0
Vegetable protein	10.0	0.0	0.0
5 Corn starch	38.3	38.3	38.3
Sucrose	20.0	20.0	20.0
Cellulose	5.0	5.0	5.0
Vitamins	1.0	1.0	1.0
Minerals	3.5	3.5	3.5
10 Choline bitartrate	0.2	0.2	0.2
Animal fat	6.0	0.0	12.0
Vegetable oil	6.0	12.0	0.0

Table 7

	Diet #1	Diet #2	Diet #3
15 T-chol. concentration	55.7±8.3	73.3±14.3*	87.0±15.2*
HDL-chol. concentration	45.7±14.9	51.1±15.2	49.5±10.3
F-chol. concentration	28.1±7.7	38.4±9.4	46.9±9.6**
TG concentration	135.7±35.7	185.8±42.1*	175.6±39.1
20 PL concentration	95.2±12.1	115.5±18.2	131.5±20.8**

\* :  $p < 0.05$  \*\* :  $p < 0.01$  (statistically significant against Diet #1)

## 25 Experiment 3

### Clinical study

Using the sausage prepared in Example 1, clinical study was carried out with 13 adult male volunteers, whose plasma-cholesterol levels were somewhat higher than normal range. Depending on the Helsinki Declaration, informed consent had been obtained from each volunteer. Three periods were set; one-week pre-observation period before a test period, two-week test period (administration of 135-g sausage equivalent to approximately 11-g soy protein a day) and one-week post-observation period after the test period.

During the entire period, each volunteer had been asked what he ate, nutritionally checked and advised to take diet of 110% and 120-130% higher than energy and fat of adequate daily intake, respectively. Each volunteer had been advised to take invariable amounts of total fat, animal fat, vegetable oil, protein, carbohydrate and total energy, too. Blood was collected and body weight was checked at hunger of each volunteer immediately before beginnings of the pre-observation and the test periods and immediately after ends of the test and the post-observation periods. Blood was examined for plasma lipids and other components. Finally, each volunteer was examined by a clinician.

With body weigh during the entire period, some of the volunteers gained their weight because of intake of energy-rich diets, although difference was not significant. No physical disorder was noticed by the doctor.

Changes in total plasma-cholesterol, plasma-HDL-cholesterol, and plasma-tryglyceride levels are shown in Figs. 1, 2 and 3, respectively. Total plasma-cholesterol and plasma-tryglyceride levels decreased during the test period. On the contrary, levels of plasma HDL cholesterol, which has been recognized to prevent coronary heart disease, increased significantly during the test period.

From these findings, it was elucidated that the meat products of the invention effectively improved such plasam lipids as cholesterol of man with light hypercholesterolemia, even if he took somewhat excessive energy and animal fat.

#### Example 4

A 2.0-kg portion of porcine thigh meat and 1.0-kg chicken breast meat were ground. They were blended with 1.5 kg of 5-mm chopped onion for 2 min at 12 rpm, and then with 2.0 kg of ice/water, 80 g of salt, 80 g of sugar, 60 g of spices, 500 g of salad oil, 2.5 kg of crust, and 1.3 kg of soy protein isolate (New Fuji-Pro HN) for 5 min at 12 rpm.

Thus prepared batter was formed as hamburger steak, steam-cooked for 15 min to an internal temperature of 80°C, cooled, chilled and vacuum-packaged with sauce. Thus the meat product (hamburger steak) of the invention was prepared. Nutrient analysis data and fatty-acid components of the prepared hamburger steak are shown in Tables 8 and 9, respectively. As a comparison, inventor-analyzed data of a conventional product are also indicated.

Fatty-acid components of the hamburger steak prepared with other vegetable oil in place of the salad oil are listed in Table 10.

Table 8

	Hamburger steak of the invention	Conventional hamburger steak
Moisture	63.4	59.8
Protein	13.7	10.5
Fat	7.6	17.4
Carbohydrate	12.4	10.4
Fiber	0.3	0
Ash	2.6	1.9
Energy (Kcal)	180.0	240.2



Table 9

Fatty acid			Fatty-acid composition (%)	
			Hamburg steak of the invention	Conventional hamburg steak
5	Myristic acid	C14:0	1.0	1.6
	Myristoleic acid	C14:1	0.1	0.4
	Pentadecanoic acid	C15:0	0.0	0.3
	Palmitic acid	C16:0	15.4	24.5
	Palitoleic acid	C16:1	1.8	3.3
10	Heptadecanoic acid	C17:0	0.2	0.7
	Heptadecenoic acid	C17:1	0.2	0.6
	Stearic acid	C18:0	6.9	10.4
	Oleic acid	C18:1	43.1	44.2
	Linoleic acid	C18:2 (n-6)	19.4	9.4
15	Linolenic acid	C18:3 (n-3)	5.0	0.7
	Arachidic acid	C20:0	0.3	0.3
	Icosenoic acid	C20:1	0.8	0.4
	Arachidonic acid	C20:4 (n-6)	0.1	0.5
	Others		5.7	2.9
20	P/S ratio		1.03	0.28
	Saturated fatty acid		24	38
	Mono-unsaturated fatty acid		46	49
	Poly-unsaturated fatty acid		25	11

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Table10

Fatty acid	Fatty-acid composition (%)										
	Soy- bean oil	Rape- seed oil	Saff- lower oil	Sesame oil	Rice- bran oil	Olive oil	Corn oil	Sun- flower oil	Cotton seed oil	Peanut oil	
Myristic acid	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.3	1.0	
Myristoleic acid	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
Pentadecanoic acid	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Palmitic acid	17.5	14.5	16.1	16.9	20.1	17.3	17.9	15.8	22.0	18.2	
Palitoleic acid	1.8	1.9	1.8	1.9	1.9	2.1	1.8	1.8	2.1	1.8	
Heptadecanoic acid	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	
Heptadecenoic acid	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	
Stearic acid	7.6	6.6	7.0	8.3	6.5	7.3	6.8	7.5	6.9	7.7	
Oleic acid	31.7	47.9	26.6	38.5	39.3	55.5	36.5	29.2	28.9	40.5	
Linoleic acid	29.6	14.9	40.8	25.7	21.3	9.6	28.3	37.6	31.4	21.7	
Linolenic acid	4.1	5.4	0.4	0.6	1.0	0.7	1.0	0.7	0.6	0.4	
Arachidic acid	0.2	0.3	0.1	0.4	0.4	0.1	0.1	0.1	0.2	0.9	
Icosenoic acid	0.3	1.0	0.3	0.4	0.5	0.3	0.3	0.3	0.3	0.8	
Arachidonic acid	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
Others	5.5	5.9	5.3	5.7	7.3	5.5	5.7	5.4	5.6	6.3	
P/S ratio	1.28	0.91	1.70	0.99	0.79	0.40	1.14	1.56	1.05	0.79	
Saturated fatty acid	26	23	24	27	28	26	26	25	31	28	
Mono-unsaturated fatty acid	34	51	29	41	42	58	39	32	32	43	
Poly-unsaturated fatty acid	34	21	41	26	22	10	30	38	32	22	

P/S ratio: Poly-unsaturated fatty acids (C18:1, C18:3, C20:4)/Saturated fatty acids (C14:0, C15:0, C16:0, C17:0, C18:0, C20:0)

## CLAIMS

1. Meat products comprising fat contents less than halves of those of conventional meat products and soy protein, and possessing plasma-cholesterol-suppressing property.
2. The meat products claimed in claim 1, wherein the meat products comprise approximately the same contents of vegetable oil and animal fat as lipids.
3. The meat products claimed in claim 2, wherein the vegetable oil is at least one of soy-bean oil, rape-seed oil, safflower oil, sesame oil, and rice-bran oil.
4. The meat products claimed in claim 2, wherein fatty-acid composition (%) of lipids are myristic acid, 0.5 - 1.5; myristoleic acid, 0 - 0.2; pentadecanoic acid, 0; palmitic acid, 13.0 - 22.0; palmitoleic acid, 1.5 - 2.5; heptadecanoic acid, 0 - 0.3; heptadecenoic acid, 0 - 0.3; stearic acid, 5.0 - 9.0; oleic acid, 24.0 - 60.0; linoleic acid, 9.0 - 45.0; linolenic acid, 0.2 - 6.0; arachidic acid, 0.1 - 1.0; icosanoic acid, 0.2 - 1.0; and arachidonic acid, 0 - 0.2.
5. The meat products claimed in claim 1, wherein the meat products comprise 1 to 20 g of soy protein against 100 g of the products.
6. The meat products claimed in claim 5, wherein the soy protein is soy protein isolate.
7. The meat products claimed in any of claims 1 to 6, wherein the meat products are sausages of pork sausage, Wiener sausage, Frankfurt sausage, Bologna sausage and the like, loaves, hams, bacons, corned beef, hamburger steak, meat balls, such delicatessen as Gyoza and Shumai, fresh sausages, bratwursts, ground meat, and seasoned meat.
8. A use method comprising administration of the meat products claimed in claim 1 to man.
9. The use method of the meat products claimed in claim 8, wherein lipids in the meat products comprise approximately the same contents of vegetable oil and animal fat.

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- 10. The use method of the meat products claimed in claim 8 or 9, wherein the meat products are sausages of pork sausage, Wiener sausage, Frankfurt sausage, Bologna sausage and the like, loaves, hams, bacons, corned beef, hamburger steak, meat balls, such delicatessen as Gyoza and Shumai, fresh sausages, bratwursts, ground meat, and seasoned meat.

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## ABSTRACT

The present invention provides meat products comprising fat contents less than halves of those of conventional meat products and soy protein, and possessing plasma-cholesterol-suppressing property. Due to reduced fat contents and addition of soy protein with the plasma-cholesterol-suppressing property, the meat products of the invention can improve plasma lipids without reducing favorable texture and taste of the meat products.

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#3  
**BIRCH, STEWART, KOLASCH & BIRCH, LLP**

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FOR PATENT AND DESIGN APPLICATIONS**

ATTORNEY DOCKET NO  
2520-109P

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As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor (if only one inventor is named below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:\*

Insert Title

MEAT PRODUCTS WITH PLASMA-CHOLESTEROL-LEVEL

SUPPRESSING PROPERTY

Check Box If  
Appropriate -  
For Use Without  
Specification  
Attached

the specification of which is attached hereto unless the following box is checked:

☒ was filed on \_\_\_\_\_ as United  
States Application Number 08/952,475 or  
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I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof, or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (six months for designs) prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows.

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Prior Foreign Application(s)

Priority Claimed

Insert Priority  
Information  
(if appropriate)

<u>146814/1995</u> (Number)	<u>Japan</u> (Country)	<u>05. 21. 1995</u> (Month/Day/Year Filed)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Month/Day/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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(Application Number)

(Filing Date)

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(Filing Date)

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Application No

Date of Filing (Month/Day/Year)

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(Filing Date)

(Status — patented, pending, abandoned)

065029-5425630

I hereby appoint the following attorneys to prosecute this application and/or an international application based on this application and to transact all business in the Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the attorneys identified below, unless the inventor(s) or assignee provides said attorneys with a written notice to the contrary:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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APPROVED	O.G. FIG.	
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Fig. 1

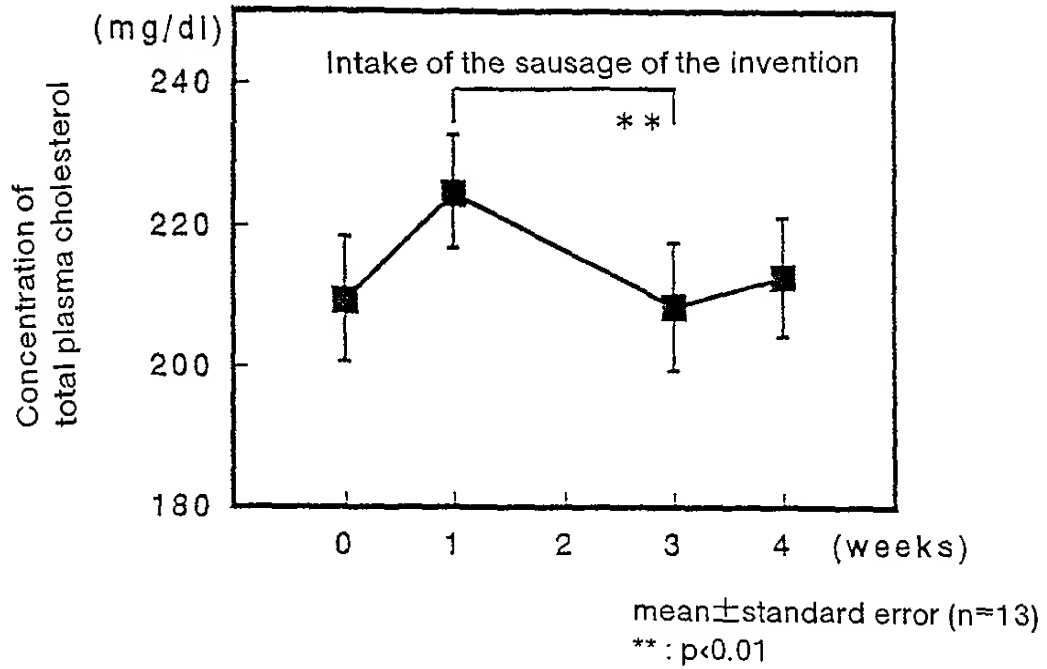


Fig. 2

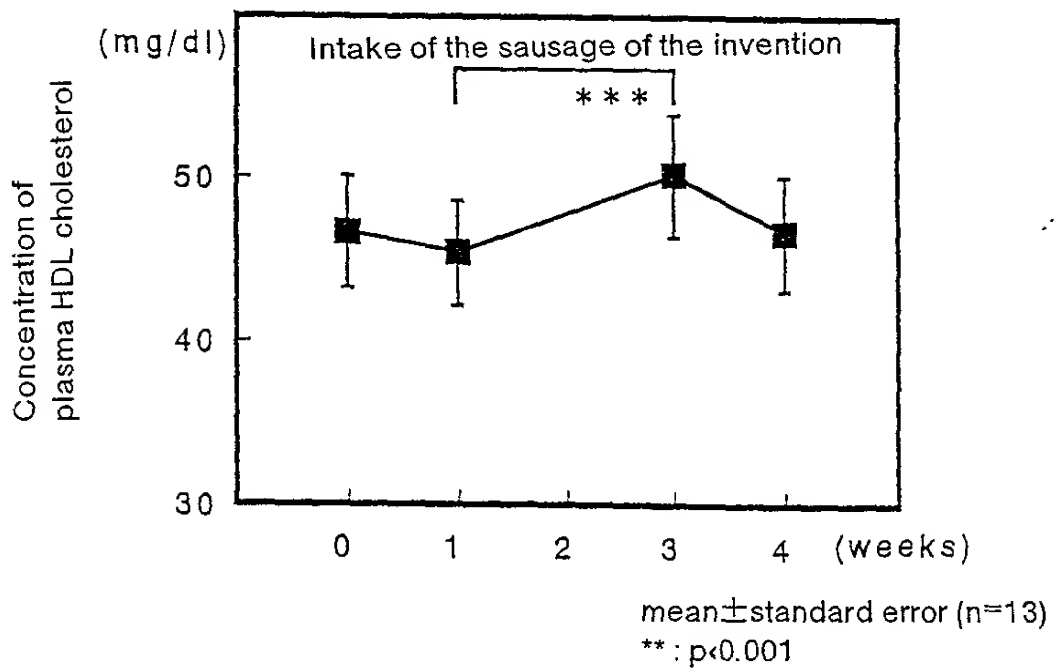
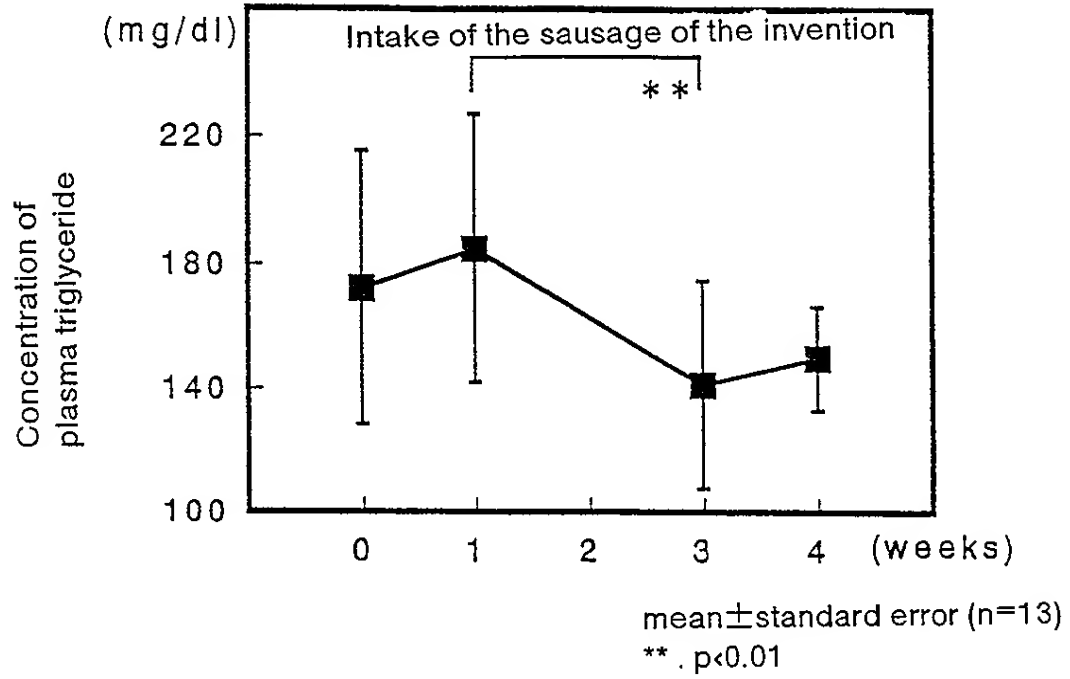




Fig. 3



08/952475-03098

Title: MEAT PRODUCTS WITH PLASMA-CHOLESTEROL-LEVEL...

Inventor(s) Name: MORIMATSU et al

Docket No.: 2520-109P

Date Filed: 11/21/97

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105 Rec'd PCT/PTO 21 NOV 1997

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